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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/029,981 | 12/31/2001 | Toshinari Sakurai | | 6062 |

7590 01/29/2004
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| | |
|---------------------------|--------------|
| EXAMINER | |
| PRATS, FRANCISCO CHANDLER | |
| ART UNIT | PAPER NUMBER |
| 1651 | |

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/029,981 | SAKURAI ET AL. |
| | Examiner | Art Unit |
| | Francisco C Prats | 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10-14 and 21-27 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10-14 and 21-27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed November 20, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 10-14 and 21-27 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14 and 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly added language following the new "wherein" clause, beginning at line 36 of claim 10, renders claim 10 and its dependents indefinite. The new language adds process steps which must be performed by the claimed apparatus. Because this new process language fails to provide any structural limitations to the apparatus claims, it is unclear what applicant intends to

Art Unit: 1651

encompass by the present claim language. See, e.g., MPEP § 2173.05(p), item "II", discussing the impropriety of claims directed to both products and processes. In short, the claims are directed to an apparatus. The new claim language recites process steps which the apparatus must perform. Because the new process-style claim language does not set forth any ascertainable structural limitations on the claimed apparatus, it is not clear how the new claim language defines the apparatus. Note that claim 27 similarly recites a heating step, which also fails to delimit any structure required in the claimed apparatus.

The recitation "crushed things of glass beads" at line 3 of claim 24 is indefinite because it is not clear whether the glass beads are crushed, or whether the claim intends to encompass anything which has been crushed by a glass bead.

The recitation "low concentration saline" in claim 25 is indefinite because it is not clear what concentrations are encompassed by "low" and what concentrations are not encompassed.

Claim Rejections - 35 USC § 103

Claims 10-14 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al (U.S. Pat. 5,389,339) in view of Kopaciewicz (U.S. Pat. 6,048,457)).

Petschek discloses a computer-controlled automated apparatus for the purification of DNA from biological samples. Petschek's apparatus comprises a syringe pump as required by claim 16. See column 2, lines 61-65:

The means for withdrawing fluid from the sample tubes preferably includes an air cylinder operably connected to the pipet arm pipetting end. The air cylinder may include a movable piston for varying the volume of the air cylinder

Note specifically that a pump containing a "movable piston" anticipates the "syringe pump" recited in applicant's claims. See also figure 2A, item 16a, clearly disclosing a syringe pump.

Figure 2A of Petschek also discloses the movable nozzle connected via a pipe to the syringe pump. See also Fig. 1B, disclosing the movable nozzle and holder, item 58, as well as the elongated pipette tips, items 80 and 81, which may be detachably connected to the nozzle. Note that Petschek is considered to meet the new process limitations requiring fluid sample sucking and discharging, based on the fact that Petschek's apparatus clearly is capable of performing these

tasks, as well as being able of enclosing a solid phase containing silica.

Petschek differs from the cited claims in that Petschek does not employ the use of silica-containing pipette tips as recited in the claims. However, Kopaciewicz discloses that the silica-containing pipette tips disclosed therein are suitable for use in the preparation of DNA from biological samples. See Examples 14, 15 and 17, at cols. 13 and 14. Note specifically that Kopaciewicz discloses that a variety of forms of silica binding material may be used in the disclosed pipette tips, thereby suggesting the various forms of silica recited in applicant's claims. See Kopaciewicz at column 4, lines 54-59. ("The term "particles" as used herein is intended to encompass particles having regular (e.g., spherical) or irregular shapes, as well as shards, fibers and powders, including metal powders, plastic powders (e.g., powdered polystyrene), normal phase silica, fumed silica and activated carbon.")

Kopaciewicz discloses that advantages of the silica-containing pipette tips disclosed by Kopaciewicz include the ability to purify desired products from very small samples, as well as simplicity and economy of manufacture. Thus, the artisan of ordinary skill, recognizing from Kopaciewicz the advantageousness of silica-containing pipette tips, clearly

would have been motivated to have used those pipette tips in the automated apparatus of Petschek, reasonably expecting that the advantages of the silica-containing pipette tips would be conveyed to Petschek's apparatus. A holding of obviousness is therefore required.

All of applicant's argument has been fully considered but is not persuasive of error. While applicant urges that it is unexpected that the use of two different and discrete eluting solutions produces an unexpected advantage with respect to DNA yield vis-à-vis the use of a single eluting solution, the prior art apparatus clearly can be configured to perform this process. More importantly, the new process limitations to the apparatus do not distinguish the claimed apparatus because they do not set forth any structural difference between the claimed apparatus and the prior art apparatus. On the current record, the only structural difference between the claimed apparatus and the apparatus of Petschek is the presence of a silica-filled pipette tip. However, as discussed above, Kopaciewicz clearly discloses that such pipette tips are advantageous when used in applications requiring DNA purification. Thus, one of ordinary skill clearly would have been motivated to have used Kopaciewicz's silica-filled DNA-eluting pipette tips on

Petschek's DNA-purifying apparatus. The rejection must therefore be maintained.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco

Art Unit: 1651

C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP